

September 7, 2000

MEMORANDUM

SUBJECT: Thiabendazole (060101) Reregistration Case No. 2760. **Revised Product and Residue Chemistry Chapters for the Thiabendazole Reregistration Eligibility Decision (RED)**. DP Barcode D267871.

FROM: Thurston Morton, Chemist
Reregistration Branch 4
Health Effects Division (7509C)

THRU: Susan Hummel, Branch Senior Scientist
Reregistration Branch 4
Health Effects Division (7509C)

TO: Beth Edwards/Susan Lewis
Reregistration Branch 1
Special Review and Reregistration Division (7508C)

Attached are the revised Product and Residue Chemistry Chapters to the Thiabendazole RED. The chapters were initially assembled by Dynamac Corporation under supervision of HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies and addenda.

EXECUTIVE SUMMARY:

Product Chemistry

- All pertinent data requirements concerning the thiabendazole TGAI are satisfied for the EPA Reg No. 100-917 and EPA Reg. No. 100-963 technical products; however, a revised CSF is required.
Also the new data requirement concerning UV/visible absorption for the pure active ingredient (PAI) (OPPTS 830.7050) remains outstanding.

Residue Chemistry

- The existing data base for thiabendazole is substantially complete. Plant and livestock metabolism data provide adequate identification/characterization of the terminal residues. Sufficient crop field trial data are available to reassess many of the thiabendazole tolerances for raw and processed plant commodities.
- Additional data are required for multiresidue method testing for the thiabendazole metabolites benzimidazole and 5-hydroxy-thiabendazole.
- Additional storage stability data are required for sweet potatoes.
- Additional residue data are required for benzimidazole (free and conjugated) in/on cantaloupe and strawberry from foliar application of thiabendazole.
- Residue data are required on thiabendazole and benzimidazole residues in/on wheat, dry beans (if registrant intends to support due to numerous SLNs), and soybeans grown from seed treated with thiabendazole. No residue data are available for these use patterns.
- A processing study is required for the processed fractions of soybeans.
- HED has reassessed the tolerances for livestock commodities.

Dietary Exposure/Risk Assessment

- Anticipated residues (DP Barcode D267542, T. Morton, 9/7/00) will be provided to DEEM for all commodities and should be used when calculating the dietary risk assessment associated with the RED. Although the database for thiabendazole is substantially complete, additional data are needed to eliminate the uncertainties associated with the exposure/risk assessment as outlined below. The anticipated residue values are the best estimates HED can provide using the residue data available at the time of the RED. These values have an inherent uncertainty associated with variations in analytical methods, geographical representation of field trials, seasonal variation of residue levels, etc.

cc : Chem F, Chron F. Morton , Shallal

RDI:ChemSAC: 10/20/99; SVH:9/7/00

TM, Thurston Morton, Rm. 816D CM2, 305-6691, mail code 7509C

THIABENDAZOLE
PC Code 060101; Case 2670
D267871

Reregistration Eligibility Decision
Residue Chemistry Considerations

December 8, 1999

Contract No. 68-D4-0010

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
1910 Sedwick Road
Building 100, Suite B
Durham, NC 27713

THIABENDAZOLE

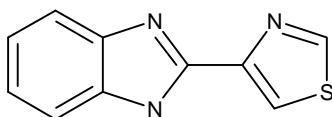
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Codes 060101 and 060102; Case No. 2670

DESCRIPTION OF CHEMICAL

Thiabendazole [2-(4-thiazolyl) benzimidazole] is a systemic fungicide used primarily for control of molds and fungal diseases on various fruits and vegetables.



Empirical Formula:	C ₁₀ H ₇ N ₃ S
Molecular Weight:	201.26
CAS Registry No.:	148-79-8
PC Codes:	060101 060102 (hypophosphite salt)

IDENTIFICATION OF ACTIVE INGREDIENT

Thiabendazole technical is a colorless crystalline solid with a melting point of 304-305 C, bulk density of 25-30 cc (tapped), octanol/water partition coefficient (K_{ow}) of 240-285 at pH 7, and vapor pressure of 4 x 10⁻⁹ mm Hg at 25 C. Thiabendazole is soluble in water at 0.028-0.030 mg/mL at 25 C, and is soluble in organic solvents at 0.004 mg/mL in hexane, 0.195 mg/mL in toluene, 2.13 mg/mL in ethyl acetate, 2.36 mg/mL in chloroform, 2.90 mg/mL in acetone, and 8.72 mg/mL in methanol at 25 C.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 10/23/98 identified two thiabendazole manufacturing-use products (MP) registered under PC Code 060101: the Novartis Crop Protection, Inc. 98.5% T (EPA Reg. Nos. 100-917 and 100-963). No MPs are registered under PC Code 060102 (hypophosphite salt). The Novartis product (EPA Reg. No. 100-917) was registered 8/98; the CSF dated 11/21/97 obtained from the product jacket indicates that the

product is repackaged from a technical product which was canceled 7/21/98. Novartis must identify the current source product. Only the registered Novartis 98.5% T/TGAI is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Thiabendazole Phase 4 Review dated 2/21/91 by C. Olinger determined that additional data were required concerning density, dissociation constant, pH, and stability (OPPTS 830.7300, 7370, 7000, and 6313); product chemistry data submissions for remaining data requirements were determined to be adequate for Phase 5 review. The current status of the product chemistry data requirements for the thiabendazole T/TGAI is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Most pertinent product chemistry data requirements are satisfied for the Novartis 98.5% T/TGAI; additional data are required concerning certified limits and UV/visible absorption (OPPTS 830.1750 and 7050). Provided that the registrant submits the data required in the attached data summary table for the 98.5% T/TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process for the thiabendazole technical product have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of thiabendazole with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): 4564
Subject: Memo unavailable
From: K. Dockter
To:
Dated: 4/21/89
MRID(s): 40789801

CBRS No(s): 5187
Subject: EPA Reg. No. 618-67. Thiabendazole. [RD Data Review Record ID No.: 060101] 63-13
Data Submitted in Response to DCI.
From: M. Nelson
To: J. Ellenberger/R. Whithers
Dated: 6/13/89
MRID(s): 41025001

CBRS No(s): 5399
Subject: Thiabendazole - Comprehensive Data Call-In Notice - Merck and Company - EPA
Registration No. 618-67.
From: G. Makhijani
To: J. Ellenberger/R. White and R. Engler
Dated: 7/17/89
MRID(s): 41083501

CBRS No(s): 5400
Subject: EPA Reg. No. 618-67. Thiabendazole. 63-8, -10, -16 Data Submitted in Response to DCI.
From: M. Nelson
To: J. Ellenberger/R. Whithers
Dated: 7/25/89
MRID(s): 40947301 and 40947302

CBRS No(s): 6043, 6044, and 6045
Subject: ID #060101, -02. Thiabendazole: Product Chemistry in Response to Data Call In.
[Supplement to MRID #00047895, #00047980, #00051865, #00029108, #00125601;
amendment to MRID #40789814 and #40835501]
From: W. Anthony
To: F. Rubis
Dated: 3/12/90
MRID(s): 00029108, 00047895, 00047980, 00051865, 00125601, 40835501, and 41258204

CBRS No(s): 13697
DP Barcode(s): D203296
Subject: Thiabendazole Reregistration. List B Chemical No. 060101; Case No. 2670. Merck & Co.,
Inc. Response to the Product Chemistry Data Requirements Regarding Stability (Guideline #
63-13).
From: F. Toghrol
To: B. Briscoe
Dated: 7/14/94
MRID(s): 43172801

DP Barcode(s): D250741 and D250742
Subject: Review of Thiabendazole Product Chemistry Blowbacks.
From: K. Dockter
To: William Sproat
Dated: 12/21/98
MRID(s): 40789801 and 41473301

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00029108 Merck & Company, Incorporated (19??) Basic Manufacturing Process for Formulation Mertect 340-F.
(Unpublished study received Aug 1, 1978 under 618-75; CDL:099237-B)

00047895 Merck & Company, Incorporated (1970?) The Identity, Physical and Chemical Properties of Thiabendazole. (Unpublished study received Aug 7, 1974 under 5F1537; CDL:094556-B)

00047980 Merck & Company, Incorporated (19??) Confidential Formula: [Thiabendazole]. (Unpublished study received May 15, 1968 under 8F0724; CDL:093034-C)

00125601 Merck & Co., Inc. (1968) The Name, Chemical Identity, and Composition of the Pesticide Chemical: [Thiabendazole]. (Compilation; unpublished study received Aug 28, 1970 under 1F1031; CDL:093340-B)

00051865 Merck & Company, Incorporated (1970) The Identity, Physical and received Jun 21, 1974 under 4F1518; CDL:094030-B)

40789801 Justin, J. (1988) Thiabendazole: Product Chemistry: Supplement to MRID No. 47895: Project ID. PC-MRK-3. Unpublished study prepared by Merck & Co., Inc. 30 p.

40835501 Justin, J. (1988) Thiabendazole: Product Chemistry: Supplement to MRIDs Nos: 00047895; 00047980; 00051865; 00029108; 00125601: Project ID: PC TM 61. Unpublished study prepared by Merck & Co., Inc. 82p.

40947301 Rose, K.; Kauppila, K. (1988) Thiabendazole: Product Chemistry: Lab ID: 159-88-0144-AS-001. Unpublished study prepared by Ricerca, Inc. 72 p.

40947302 Book, D.; Thomas, E. (1988) Thiabendazole: Product Chemistry: Lab ID: 1959-88-0145-AS-001. Unpublished study prepared by Ricerca, Inc. 71 p.

41025001 Justin, J. (1989) Thiabendazole: Stability of 2, -(4-Thiazolyl Benzimidazole: Proj. ID CHEM - 89. Unpublished study prepared by Merck & Co., Inc. 10 p.

41083501 Justin, J. (1989) Thiabendazole: Analysis and Certification of Ingredient Limits: Project ID: PC 622623. Unpublished study prepared by Merck & Co., Inc. 50 p.

41258204 Justin, J. (1989) Thiabendazole - Chemical Identity: Amendment to MRID No. 40789814: Project ID DC 618. Unpublished study prepared by Merck & Co., Inc. 10 p.

41473301 Justin, J. (1990) Thiabendazole: Additional Product Chemistry (Supplement to MRID 41083501). Lab Project Number: PC 622623. Unpublished study. 9 p.

43172801 Boatright, A. (1994) Determination of the Stability of Thiabendazole in Aqueous Solutions of Al+3, Fe+3, and Sn+2 and in the Presence of Sunlight: Lab Project Number: 618-67/63-13. Unpublished study prepared by Merck Research Labs, Merck & Co., Inc. 31 p.

Case No. 2670
PC Code 060101

Case Name: Thiabendazole
Registrant: Novartis Crop Protection, Inc.
Product(s): 98.5% T (EPA Reg No. 100-917)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204 ³
830.1600	Description of materials used to produce the product	Y	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204 ³
830.1620	Description of production process	Y	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204 ³
830.1670	Discussion of formation of impurities	Y	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204 ³
830.1700	Preliminary analysis	Y	41083501 ⁴ , 41473301
830.1750	Certified limits	N ⁵	41083501 ⁴ , 41473301
830.1800	Enforcement analytical method	Y	41083501 ⁴
830.6302	Color	Y	40789801
830.6303	Physical state	Y	40789801
830.6304	Odor	Y	40789801
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	41025001 ⁶ , 43172801 ⁷
830.7000	pH	Y	40789801 ⁸
830.7050	UV/Visible absorption	N ⁹	
830.7200	Melting point/melting range	Y	40789801
830.7220	Boiling point/boiling range	N/A ¹⁰	
830.7300	Density/relative density/bulk density	Y	40789801 ⁸
830.7370	Dissociation constants in water	Y	40947302 ¹¹
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	40789801
830.7840	Water solubility: column elution method; shake flask method	Y	40947301 ¹¹
830.7950	Vapor pressure	Y	40789801

¹ Y = Yes; N = No; N/A = Not Applicable. Conclusions are based on data submitted by Merck and Company; Novartis must identify the current source product.

² **Bolded** references were determined to be acceptable for Phase 5 review in the Thiabendazole Phase 4 review dated 2/21/91 by C. Olinger and are K. Dockter, 12/21/98 (DP Barcodes D250741 and D250742); unbolded references were determined to be adequate for Phase 5 review in the Phase 4 review and were subsequently reviewed under CBRS Nos. 6043, 6044, and 6045, 3/12/90, W. Anthony; and the remaining references were reviewed as noted.

³ CBRS Nos. 6043, 6044, and 6045, 3/12/90, W. Anthony.

⁴ CBRS No. 5399, 7/17/89, G. Makhijani.

⁵ A revised CSF must be submitted on EPA Form 8570-4, which identifies the current source product and which reflects modified nominal concentrations and/or certified limits for the active ingredient and two impurities.

⁶ CBRS No. 5187, 6/13/89, M. Nelson.

⁷ CBRS No. 13697, D203296, 7/14/94, F. Toghrol.

⁸ CBRS No. 4564, 4/21/89, K. Dockter.

⁹ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

¹⁰ Data are not required because the TGAI is a solid at room temperature.

¹¹ CBRS No. 5400, 7/25/89, M. Nelson.

Case No. 2670
PC Code 060101

Case Name: Thiabendazole
Registrant: Novartis Crop Protection, Inc.
Product(s): 98.5% T (EPA Reg No. 100-963)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204 ³ , 44724601 ¹²
830.1600	Description of materials used to produce the product	Y	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204 ³
830.1620	Description of production process	Y	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204 ³
830.1670	Discussion of formation of impurities	Y	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204 ³
830.1700	Preliminary analysis	Y	41083501 ⁴ , 41473301 , 44724602 ¹²
830.1750	Certified limits	N ⁵	41083501 ⁴ , 41473301
830.1800	Enforcement analytical method	Y	41083501 ⁴
830.6302	Color	Y	40789801
830.6303	Physical state	Y	40789801
830.6304	Odor	Y	40789801
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	41025001 ⁶ , 43172801 ⁷
830.7000	pH	Y	40789801 ⁸
830.7050	UV/Visible absorption	N ⁹	
830.7200	Melting point/melting range	Y	40789801
830.7220	Boiling point/boiling range	N/A ¹⁰	
830.7300	Density/relative density/bulk density	Y	40789801 ⁸
830.7370	Dissociation constants in water	Y	40947302 ¹¹
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	40789801
830.7840	Water solubility: column elution method; shake flask method	Y	40947301 ¹¹
830.7950	Vapor pressure	Y	40789801

¹ Y = Yes; N = No; N/A = Not Applicable. Conclusions are based on data submitted by Merck and Company; Novartis must identify the current source product.

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³ CBRS Nos. 6043, 6044, and 6045, 3/12/90, W. Anthony.

⁴ CBRS No. 5399, 7/17/89, G. Makhijani.

⁵ A revised CSF must be submitted on EPA Form 8570-4, which identifies the current source product and which reflects modified nominal concentrations and/or certified limits for the active ingredient and two impurities.

⁶ CBRS No. 5187, 6/13/89, M. Nelson.

⁷ CBRS No. 13697, D203296, 7/14/94, F. Toghrol.

⁸ CBRS No. 4564, 4/21/89, K. Dockter.

⁹ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

¹⁰ Data are not required because the TGAI is a solid at room temperature.

¹¹ CBRS No. 5400, 7/25/89, M. Nelson.

¹² D252511, 2/3/99, S. Malak.

THIABENDAZOLE

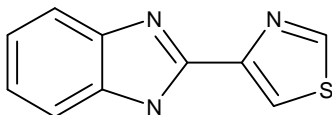
REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 060101; Case 2670

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THIABENDAZOLE



REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 060101; Case 2670

INTRODUCTION

Thiabendazole [2-(4-thiazolyl)benzimidazole] is a fungicide registered for use on bananas, carrots, citrus fruits, mushrooms, pome fruits, potatoes, soybeans, tobacco, and wheat. The registrant wishes to support tolerances with no US registrations for papaya, mango, cantaloupe, avocado, and strawberry. Thiabendazole was previously manufactured by Merck & Co., Inc. under the trade name Mertect. The technical active ingredient and all of Merck's end-use products were transferred (8/97) to Novartis Crop Protection, Inc., who is now the basic producer.

Thiabendazole formulations registered to Novartis for use on food/feed crops and tobacco include two flowable concentrate (FIC) formulations, a water dispersable granular (dry flowable, DF) formulation, and a ready-to-use (RTU) formulation. These products may be applied as a pre-planting application (potato seed-pieces or wheat seed treatment), chemigation (mushroom), foliar (cantaloupe, strawberry), or post-harvest applications.

REGULATORY BACKGROUND

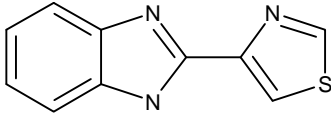
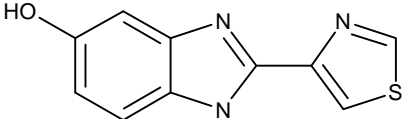
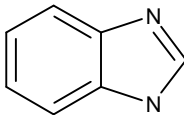
Thiabendazole is a List B reregistration chemical and was the subject of a Phase 4 Review dated 2/20/91. A Data Call-In (DCI) Notice for thiabendazole was also issued 6/12/91. These documents summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Several submissions of data have been received since the Phase 4 Review was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of thiabendazole.

Tolerances for residues of thiabendazole in/on plant raw agricultural commodities (RACs) and processed plant commodities have been established under 40 CFR §180.242(a). Tolerances for residues in/on plant commodities range from 0.02 ppm in/on sweet potatoes to 15 ppm in/on cantaloupes; a 40 ppm tolerance has also been established for residues in/on mushrooms.

Tolerances for residues of thiabendazole in/on processed commodities range from 3 ppm in wheat milled fractions to 35 ppm in dried citrus pulp. Tolerances have also been established for the combined residues of thiabendazole and its metabolite, 5-hydroxy-thiabendazole, in milk at 0.4 ppm and in eggs, meat, meat-by-products (mbyp) and fat of livestock at 0.1 ppm [§180.242(b)].

The HED Metabolism Assessment Review Committee (T. Morton, 12/2/99, D261103) concluded the thiabendazole residues of concern in plants include thiabendazole and its metabolite benzimidazole (free and conjugated). The HED Metabolism Committee (L. Cheng, 2/14/92) concluded that thiabendazole residues to be regulated in animal commodities will include thiabendazole, 5-hydroxy-thiabendazole (free and conjugated) and benzimidazole. The chemical names and structures of thiabendazole and its metabolites of concern are depicted in Figure A.

Figure A. Chemical name and structure of thiabendazole and its residues of concern in plant and animal commodities.

Common Name/Chemical Name	Chemical Structure
Thiabendazole 2-(4-thiazolyl)benzimidazole	
5-Hydroxy-thiabendazole (free and conjugated) 2-(4-thiazolyl)-5-hydroxy-benzimidazole	
Benzimidazole (free and conjugated)	

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS 860.1000). As a result of changes to Table 1, additional thiabendazole residue data are now required for some commodities; these data requirements have been incorporated into this document. These new data requirements will be imposed at the issuance of the Thiabendazole RED but should not impinge on the reregistration eligibility decisions for thiabendazole. The need for revisions to dietary exposure/risk assessments will be determined upon receipt of the required residue chemistry data.

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 8/30/99 indicated that there are three thiabendazole end-use products (EPs) with uses on food/feed crops and tobacco registered to Novartis Crop Protection, Inc. These EPs are presented below.

Table 1. Thiabendazole End-Use Products with Food/Feed and Tobacco Uses Registered to Novartis.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
100-887 ^a	5/98	40% RTU	Mertect [®] 40 Antimycotic
100-889	10/93	3.8 lb/gal FIC	Mertect [®] 340-F Fungicide
100-890	10/93	2.7 lb/gal FIC	Mertect [®] LSP Fungicide

^a This product is registered only for post-harvest use on tobacco.

A review of the above labels and supporting residue data indicate that the following label amendments are required:

- ! Any use directions for dry beans, field peas, grapes, rice, and sugar beets should be deleted from all of the registrant's labels as these uses are not being supported.
- ! Use directions for apples must be amended to specify a 30-day retreatment interval (RTI) between the postharvest aqueous dip and wax applications.
- ! Use directions for bananas must be amended to specify a maximum dip time of 1 minute.
- ! Use directions for postharvest applications to citrus must be amended as follows: a maximum of two post-harvest applications of thiabendazole to citrus fruits are allowed except in AZ and CA. The first as a dip for up to 3 minutes prior to de-greening in an aqueous suspension of thiabendazole at up to 1,000 ppm; followed by second application (after de-greening and washing) of thiabendazole at up to 3,500 ppm in wax (1 gal wax/3,500 lb of fruit). In AZ and CA, the use of an aqueous thiabendazole dip is prohibited; only a single post-harvest application of thiabendazole in wax at up to 5,000 ppm (1 gal wax/3,500 lb of fruit) is allowed.
- ! Use directions for postharvest applications to avocado, mango, and papaya must be amended to include only those uses which are supported by residue data. A review of foreign labels reveal preharvest uses on avocado and mango. Residue data must be submitted for a combination of pre- and postharvest application of thiabendazole or the preharvest use must be deleted from labels.

- ! A review of foreign labels reveal postharvest uses on cantaloupe. Residue data must be submitted for a combination of pre- and postharvest application of thiabendazole or the postharvest use must be deleted from labels. Use directions for foliar applications to cantaloupe and strawberry must be amended to include only those uses which are supported by residue data. Additional residue data are required for benzimidazole (free and conjugated) in/on cantaloupe and strawberry from this use. Also the RAC melons must be changed to specify only cantaloupe.
- ! Use directions for mushrooms must be amended limiting direct spray applications to a maximum of 0.12 lb ai/1000 ft²/application.
- ! Use directions for FIC formulations should be amended to include a maximum of three foliar applications totaling 1.51 oz ai/1000 ft² (4.11 lb ai/A) to tobacco seedlings prior to transplanting.
- ! Use directions for potatoes must be amended to specify a 30-day RTI between the two postharvest applications.
- ! The label restriction against the feeding or grazing of livestock on treated wheat forage should be deleted as this restriction is no longer permitted. Pre-grazing intervals (PGI) and pre-harvest intervals (PHI) must be proposed for wheat forage and hay.
- ! The labels must be amended to prohibit crop rotation to all crops not currently registered until the required field accumulation in rotational crop study is adequate.

A comprehensive summary of the registered food/feed use patterns of thiabendazole, based on the product labels registered to Novartis, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of thiabendazole is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of thiabendazole food/feed and tobacco uses are based on the use patterns registered by the basic producer, Novartis. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer's labels.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on soybean, sugar beet, and wheat metabolism studies. The residues of concern in plants include thiabendazole and benzimidazole, free and conjugated (L. Cheng, 3/11/92). The HED Metabolism Assessment Review Committee (T. Morton, 12/2/99, D261103) concluded that the thiabendazole residues to be regulated in plant commodities will include thiabendazole and benzimidazole, free and conjugated.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of thiabendazole residues in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. The HED Metabolism Committee (L. Cheng, 2/14/92) concluded that the thiabendazole residues to be regulated in animal commodities will include thiabendazole, 5-hydroxy-thiabendazole (free and conjugated), and benzimidazole (See Figure A).

OPPTS GLN 860.1340: Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of thiabendazole residues as currently defined. The Pesticide Analytical Manual (PAM) Vol. II lists four spectrophotofluorometric methods (Methods I, A, B, and C) for determining residues of thiabendazole *per se* in or on plant commodities, and one spectrophotofluorometric method (Method D) for determining residues of thiabendazole and 5-hydroxy-thiabendazole in milk.

In addition, the registrant has proposed new HPLC/fluorometric detection methods for determining residues of benzimidazole (free and conjugated) in/on plant commodities and residues of thiabendazole, 5-hydroxy-thiabendazole (free and conjugated), and benzimidazole in animal commodities. These methods are similar to the current enforcement methods in that solvent extracted residues are quantified fluorometrically. However, the new methods employ additional clean-up procedures and utilize HPLC/fluorescence detection for separating and quantifying residues.

The registrant has proposed a reverse-phase HPLC/fluorescence method for determining residues of benzimidazole in plant commodities. For this method, residues are first extracted with methanol (MeOH) and then the residual solids are refluxed in methanolic 3 N KOH. Extracted residues are combined, diluted with concentrated HCl, filtered, and concentrated. Residues are then diluted with 0.02 M KH_2PO_4 , adjusted to pH 5, and hydrolyzed with α -glucosidase. The resulting hydrolysate is adjusted to pH <3 and partitioned with ethyl acetate (EtOAc), discarding the organic fraction. The hydrolysate is then diluted with 2 N KOH and buffered by the addition of 2 N Na_2CO_3 . Residues are then partitioned into EtOAc, concentrated to dryness, and redissolved in 1% ammonium acetate. Total benzimidazole residues are determined by reverse-phase HPLC with fluorescence detection. The validated limit of quantitation (LOQ) for total benzimidazole residues is 0.1 ppm in/on wheat grain, straw, and processed commodities. This method has undergone a successful independent laboratory validation and was forwarded to the Analytical Chemistry Branch for Agency validation.

More recently, adequate cation-exchange HPLC/fluorescence detection methods have been used for collecting data on both thiabendazole and benzimidazole (free and conjugated) in various plant commodities.

Methods M-023, M-046, and M-049 have been used for determining residues of thiabendazole in banana, potato, and citrus commodities. In these methods, residues of thiabendazole are extracted with EtOAc, cleaned up using a propyl sulfonic acid (PRS) solid phase extraction (SPE) column, and analyzed by cation exchange HPLC using a fluorescence detector. Validated method LOQs for thiabendazole are 0.005-0.05 ppm.

Methods M-040, M-041, M-048, and M-056 have been used for determining residues of free and conjugated benzimidazole in citrus, apple, potato and banana commodities, respectively. In Methods M-040 and M-041, samples are diluted with phosphate buffer (pH 6) and free benzimidazole is extracted into EtOAc. The remaining aqueous homogenate is filtered, concentrated, and adjusted to pH ~5.5. Conjugated benzimidazole residues are then hydrolyzed with α -glucosidase. The hydrolysate is adjusted to pH 6, and released benzimidazole residues are then extracted into EtOAc, combined with free benzimidazole residues, and dried over sodium sulfate. Total benzimidazole residues are then cleaned up using a PRS SPE column. In Methods M-048 and M-056, free and conjugated benzimidazole residues are extracted with 0.025 M HCl, adjusted to pH 5, and incubated with α -glucosidase. The hydrolysate is then adjusted to pH 8, and residues are extracted into EtOAc and cleaned up using a PRS SPE column. In all four methods, total benzimidazole residues are determined by cation exchange HPLC using fluorescence detection. Validated method LOQs for thiabendazole are 0.01-0.2 ppm in/on plant commodities.

The registrant has proposed new cation exchange HPLC/fluorescence methods for enforcing tolerances in animal commodities. Method M-028.1 is for determining thiabendazole and 5-hydroxy-thiabendazole (free and conjugated) in milk, and Methods M-025.1 and M-027 are for determining thiabendazole, 5-hydroxy-thiabendazole (free and conjugated), and benzimidazole in eggs and animal tissues, respectively. Each of these methods has undergone a successful independent laboratory validation.

For Method M-028.1, residues are hydrolyzed at 85-90 °C for 4 hours using concentrated HCl, adjusted to pH 8, and extracted into EtOAc. Residues are then cleaned up using a PRS SPE column and analyzed by cation exchange HPLC using fluorescence detection. The validated LOQ is 0.05 ppm for each analyte in milk.

For Methods M-025.1 and M-027, residues in eggs and tissues are hydrolyzed at 90-95 °C for 24 hours using 6N HCl, cooled, and partitioned against EtOAc, discarding the organic fraction. Residues are then adjusted to pH 8, filtered through diatomaceous earth, and cleaned up using a PRS SPE column. Residues are analyzed by cation exchange HPLC using fluorescence detection. The validated LOQ is 0.05 ppm for each analyte in eggs and is 0.1 ppm for each analyte in tissues. Additional data are required for Method M-027. The method should be validated at levels of 0.05 ppm for each analyte.

The HPLC/fluorescence detection methods for determining residues of thiabendazole and 5-hydroxy-thiabendazole (free and conjugated) in milk (Merck Method M-028.1) and

thiabendazole, 5-hydroxy-thiabendazole (free and conjugated), and benzimidazole in animal tissues (Merck Method M-027) will be forwarded to the Analytical Chemistry Branch for validation by the Agency when additional data for M-027 is submitted. As tolerances for poultry commodities are no longer required, additional data and Agency validation are not required for Merck Method-025.1 for determining thiabendazole residues in eggs.

OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database indicates that thiabendazole is completely recovered using FDA Multiresidue Protocols A and D (PAM I Sections 242.2 and 232.4); recovery using Protocol E (PAM I Sections 211.1 and 212.1) were not reported. Data are required depicting recovery of the metabolites 5-hydroxy-thiabendazole and benzimidazole through FDA Multiresidue Protocols.

OPPTS GLN 860.1380: Storage Stability Data

With the exception of sweet potatoes, the requirements for supporting storage stability data are satisfied for all acceptable residue studies. Generally, thiabendazole residues are stable in frozen crop matrices; none of the storage stability studies showed declines in thiabendazole or benzimidazole.

The available data indicate that residues of thiabendazole are stable for up to 9 months in apples, apple juice and dried pomace stored at -15 °C; for up to 3 months in whole bananas and banana pulp stored at -20 °C; for up to 9 months in citrus fruit, oil, molasses, and pulp stored at -26 °C; for up to 28 months in mushrooms stored at -23 °C; for up to 27 months in potatoes and wet potato peel stored ≤ 0 °C; for up to 23 months in wheat grain and straw stored at ≤ -15 °C; and for up to 18 months in wheat bran and flour stored at ≤ -15 °C.

Residues of benzimidazole also are stable in mushrooms at -23 °C for up to 28 months; in whole potatoes and wet peel frozen for up to 27 months; in wheat grain and straw at ≤ -15 °C for up to 23 months and bran and flour for up to 18 months.

Data are required depicting the storage stability of thiabendazole and benzimidazole in frozen sweet potatoes stored for up to 52 months.

The available storage stability data for animal commodities indicate that residues of thiabendazole, 5-hydroxy-thiabendazole and its sulfate conjugate are stable in milk at -10 °C for up to 2 months and that residues of thiabendazole and 5-hydroxy-thiabendazole are stable in liver, kidney and muscle stored at -10 °C for up to 2.8 months. These data support the available animal feeding studies in which only residues of thiabendazole and 5-hydroxy-thiabendazole (free and conjugated) were determined. No data are available on the stability of benzimidazole in animal commodities.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

Provided that the specified amendments are made in label use directions, the requirements for magnitude of the residue data in/on plants are fulfilled for the following crops: apples, avocados, bananas, carrots, citrus fruits, mangoes, mushrooms, papayas, pears, and potatoes. Adequate field trial data depicting thiabendazole residues of concern in/on these crops following applications made according to the maximum or proposed use patterns have been submitted. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Adequate field trial data are also available for sweet potatoes pending submission of supporting storage stability data.

Residue data are required on thiabendazole and benzimidazole residues in/on wheat, dry beans (if registrant intends to support due to numerous SLNs), and soybeans grown from seed treated with thiabendazole. No residue data are available for these use patterns. Residue data was for foliar use which has been canceled.

Additional residue data are required for cantaloupe and strawberry. Application to cantaloupe and strawberry are foliar therefore, residue data for benzimidazole (free and conjugated) are required. For cantaloupe, use rate must be 0.27 lb a.i./acre with 3 applications per season and a PHI of 4 days. For strawberry use rate must be 0.56 lb a.i./acre applied once per season and a PHI of 14 days.

Data on thiabendazole residues in aspirated grain fractions derived from wheat are not required as thiabendazole is applied early in the growing season prior to seed head formation. In addition, the wheat processing study gave no indication that thiabendazole residues concentrate in the outer seed coat of wheat grain.

Data are required on thiabendazole residues in/on lentils grown from seed treated with thiabendazole (FIC) at the maximum label rate if the registrant intends on supporting this use. A Section 18 Exemption was granted for this use in 1997 (DP Barcodes D234720 and D234721, M. Ottley/B. Tarplee/N. Dodd, 8/6/97) along with a temporary tolerance of 0.1 ppm for residues in/on lentils set to expire 10/31/98. With the support of the pea and lentil industry, the Washington State Commission on Pesticide Registration, and Gustafson (the manufacturer), IR-4 began residue studies on dry peas and lentils during 1996 to support this use. However, in a recent memorandum pertaining to a meeting of the Agency with Gustafson to discuss proposed seed-treatment uses of thiabendazole (DP Barcodes D236380 and D236381, J. Herndon, 7/10/97), it was noted that Gustafson would likely be unable to pursue seed treatment uses of thiabendazole if Merck sold thiabendazole to a competitor. As Merck has sold thiabendazole to Novartis, it is unclear if Gustafson (and/or Novartis) will continue to support seed-treatment uses on lentils.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for apples, citrus fruit, potatoes and wheat. The available potato and wheat processing studies indicate that thiabendazole residues do not concentrate in any currently regulated processed commodities of potato (granules/flakes, chips, or wet peel) or wheat (bran, flour, middlings, shorts, germ). Residue data are required for the processed fractions of soybeans.

Thiabendazole residues concentrate by 1.5-1.6x in dried citrus pulp and 1.7-2.7x in citrus oil. Using a 1.6x concentration factor and the HAF residues of 5.2 ppm for whole citrus fruits, the maximum expected residues in dried pulp would be 8.3 ppm, which is below the current 10 ppm tolerance for residues in/on whole citrus fruit. Therefore, the separate tolerance for dried citrus pulp is not necessary and should be revoked. However, a tolerance is necessary for thiabendazole residues in citrus oil, based on the average concentration factor (2.4x) and the HAF residues; maximum expected residues in citrus oil would be 12.5 ppm.

The available apple processing study indicates that thiabendazole residues concentrate by 3.5x in wet apple pomace. Based on this concentration factor and the current HAF residues of 3.4 ppm in/on apples, a tolerance of 12 ppm should be established for thiabendazole residues in wet apple pomace. Thiabendazole residues also concentrated by 11.6x in dried apple pomace, but tolerances for thiabendazole residues in dried apple pomace have been revoked as it is no longer a regulated commodity.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are fulfilled. Adequate poultry and ruminant feeding studies are available depicting residues of thiabendazole and 5-hydroxy-thiabendazole in meat, milk, poultry and eggs. Although benzimidazole, a residue of concern in animals, was not determined in the feeding studies, data from the animal metabolism studies will be used to calculate residue levels of benzimidazole in animal commodities for purposes of tolerance reassessment and risk assessment. Based upon the established or reassessed tolerances for thiabendazole residues in/on animal feed items, the calculated maximum theoretical dietary burdens for livestock are 37.6 ppm for beef cattle, 26.1 ppm for dairy cattle, 5.1 ppm for hogs, and 0.16 ppm for poultry, these are calculated below. Data from the ruminant feeding study will be used to reassess tolerances in hogs.

Table 2. Calculation of maximum dietary burdens of livestock animals for thiabendazole.

Feed Commodity	% Dry Matter ^a	% Diet ^a	Tolerance (ppm) ^b	Dietary Contribution (ppm) ^c
Beef Cattle				
potato culls	20	75	10.0	37.5
wheat straw	88	10	0.5	0.06
wheat grain	89	15	0.2	0.03
TOTAL BURDEN		100		37.59
Dairy Cattle				
potato culls	20	40	10.0	20.0
wet apple pomace	40	20	12.0	6.0
wheat straw	88	10	0.5	0.06
wheat grain	89	30	0.2	0.07
TOTAL BURDEN		100		26.13
Poultry				
wheat grain	N/A	80	0.2	0.16
TOTAL BURDEN	0	100		0.16
Swine				
potato culls	N/A	50	10.0	5.0
wheat grain	N/A	50	0.2	0.1
TOTAL BURDEN		100		5.10

^a Table 1 (August 1996).

^b Current or reassessed tolerance from Table C; residues in/on potato culls is based upon the tolerance for whole potatoes.

^c Contribution = [tolerance / % DM (if cattle)] X % diet).

In the poultry feeding studies, thiabendazole was fed at levels of 2, 20, 200, and 2,000 ppm in the diet to male and female broilers (25 birds/sex/dose group) to examine residues in tissues, and to laying hens (6 hens/dose group) to examine residues in eggs. Residues of thiabendazole and 5-hydroxy-thiabendazole were determined in tissues of broilers following 7 weeks of dosing, and these residues were also determined in egg samples collected between 3-4 weeks of dosing. Although the residue data for eggs from the feeding study did not show when residues plateaued, thiabendazole residues in eggs plateaued by Day 8 in the poultry metabolism study. Based on the theoretical maximum dietary burden of 0.16 ppm for poultry, the 2 and 20 ppm dose levels are equivalent to 12.5 and 125x the maximum dietary burden, respectively. Residues of thiabendazole and 5-hydroxy-thiabendazole in tissues and eggs of poultry are summarized in the table below. Although residues of benzimidazole were not determined, benzimidazole residues would be expected to be 0.5x, 0.4x, and 0.3x the level of 5-hydroxy-thiabendazole residues in eggs, liver, and kidneys, respectively, based on data from the poultry metabolism study.

Table 3. Residue data for thiabendazole (TBZ) and 5-hydroxy-thiabendazole (5-OH-TBZ) from poultry feeding studies.

Matrix	Dose Level (ppm) ^a	TBZ (ppm)		5-OH-TBZ (ppm)		Average Total Residues (ppm) ^b
		Range	Average	Range	Average	
Fat/skin	0	0.009-0.013	0.011	0.009-0.013	0.010	0.021
	2	0.010-0.012	0.011	0.009-0.013	0.012	0.023
	20	0.010-0.015	0.012	0.010-0.013	0.012	0.024
	200	0.024-0.060	0.039	0.029-0.055	0.038	0.077
	2000	0.16-0.41	0.27	0.20-0.63	0.38	0.65
Liver	0	0.005-0.008	0.006	0.012-0.019	0.017	0.023
	2	0.006-0.012	0.008	0.014-0.029	0.019	0.027
	20	0.010-0.014	0.012	0.046-0.067	0.057	0.069
	200	0.027-0.051	0.040	0.16-0.58	0.37	0.41
	2000	0.29-0.60	0.43	1.80-5.15	3.08	3.51
Muscle	0	0.007-0.010	0.009	0.005-0.007	0.006	0.015
	2	0.007-0.009	0.008	0.006-0.008	0.007	0.015
	20	0.009-0.013	0.010	0.008-0.010	0.009	0.019
	200	0.019-0.035	0.023	0.016-0.036	0.027	0.050
	2000	0.081-0.26	0.16	0.17-0.64	0.36	0.52
Egg Yolks ^c	0	0.006-0.014	0.009	0.005-0.009	0.007	0.016
	20	0.007-0.020	0.014	0.016-0.031	0.025	0.039
	200	0.038-0.063	0.050	0.39-1.27	0.82	0.87
	2000	0.53-0.67	0.63	1.22-1.91	1.61	2.24
Egg white ^c	0	0.004-0.011	0.006	0.006-0.009 ^d	0.008	0.014
	20	0.003-0.011	0.007	0.004-0.012	0.008	0.015
	200	0.017-0.027	0.024	0.032-0.048 ^e	0.043	0.067
	2000	0.18-0.21	0.20	0.24-0.36	0.30	0.50

^a The 2 and 20 ppm dose levels are equivalent to 12.5x and 125x the maximum theoretical dietary burden, respectively

^b Sum of the average TBZ and 5-OH-TBZ residues; data from individual samples were not available.

^c Data are from eggs only collected ~3 weeks after dosing; data from the poultry metabolism indicated that residues in eggs plateaued after 8 days.

^d Excludes two outliers at 0.021 and 0.023 ppm.

^e Excludes a single outlier at 0.64 ppm.

At the 20 ppm dose level (125x), maximum residues of thiabendazole and 5-hydroxy-thiabendazole in poultry tissues were ≤ 0.015 ppm and ≤ 0.067 ppm, respectively, and likewise residues of benzimidazole would be expected to be ≤ 0.027 ppm. At the same dose level, maximum residues of thiabendazole and 5-hydroxy-thiabendazole in egg yolks were 0.02 and 0.03 ppm, respectively, and residues of benzimidazole would be expected to be 0.015 ppm. Residue

levels in whole eggs would actually be lower as residues in egg whites were considerably lower than in yolks. The LOQs for each of these analytes in the proposed enforcement methods is 0.1 ppm in tissues and 0.05 ppm in eggs. Based upon these data, HED concludes that there is no reasonable expectation of finding finite thiabendazole residues in poultry tissues and eggs [40 CFR 180.6(a)(3)] resulting from the feeding of thiabendazole treated crops to poultry. Therefore, tolerances for thiabendazole residues in poultry and eggs are not required.

In the ruminant feeding study, thiabendazole was fed to dairy cows (3 animals/dose group) at levels of 25, 75, and 250 ppm in the diet for 28 consecutive days. These dose levels are equivalent to 0.7x, 1.9x, and 6.7x the maximum theoretical dietary burden for beef cattle (37.6 ppm) and 1x, 2.9x, and 9.6x the maximum theoretical dietary burden for dairy cattle (26.1 ppm). Two of the three cows per dose group were sacrificed after 28 days of dosing and the third cow was sacrificed on Day 57, after 28 days of depuration. Milk samples were collected from treated animals on Days -1, 1, 2, 4, 7, 14, 21, and 28 of dosing and after 1, 7, 14, 21 and 28 days of depuration. Residues of thiabendazole and 5-hydroxy-thiabendazole were determined in fat, muscle, liver, kidney and milk and are summarized in the table below. Although residues of benzimidazole were not determined in the feeding study, benzimidazole residues would be expected to be 0.7x, 0.6x, and 0.6x the level of 5-hydroxy-thiabendazole residues in liver, kidneys, and muscle, respectively, based on data from the goat metabolism study. Residues of benzimidazole were not detected in milk in the metabolism study.

Residues in milk plateaued by Day 2 of dosing in the feeding study, and by days 3-5 in the goat metabolism study. Maximum residues of thiabendazole and 5-hydroxy-thiabendazole were 0.015 ppm and 0.013 ppm, respectively, in milk of cows dosed at 25 ppm (1x the maximum dietary burden for dairy cattle). The proposed enforcement method, which determines only thiabendazole and 5-hydroxy-thiabendazole, has LOQs of 0.05 ppm for both analytes; therefore, residues from the 1x feeding level would be below the LOQ. However, at the 75 ppm dose level (2.9x), maximum residues of 5-hydroxy-thiabendazole in milk were 0.108 ppm, above the LOQ for the proposed enforcement method. Based upon these data the tolerance for thiabendazole residues in milk should be lowered from 0.4 ppm to 0.1 ppm, which is the combined LOQ of thiabendazole and 5-hydroxy-thiabendazole in the proposed enforcement method.

In muscle and fat of cows from each dose group (0.7x, 1.9x, and 6.7x the dietary burden for beef cattle), residues of thiabendazole and 5-hydroxy-thiabendazole were similar to residue levels in control muscle and fat. Maximum residues of thiabendazole and 5-hydroxy-thiabendazole were 0.018 and 0.012 ppm in fat and 0.017 and 0.006 ppm in muscle. These levels are below the LOQs (each at 0.1 ppm) for these analytes in the proposed enforcement method. Based upon these data, HED concludes that there is no reasonable expectation of finding finite thiabendazole residues in meat and fat of cattle, goats, horses, and sheep resulting from the feeding of thiabendazole treated crops to livestock [40 CFR 180.6(a)(3)]. Tolerances for thiabendazole residues in fat of cattle, goats, horses, and sheep should be revoked. The tolerance for thiabendazole residues in meat of cattle, goats, horses, and sheep will be retained at 0.1 ppm to harmonize with Codex.

Maximum residues of thiabendazole and 5-hydroxy-thiabendazole were also below the proposed enforcement method LOQs (0.1 ppm) in liver and kidney of animals dosed at 0.7x the maximum dietary burden of beef cattle. However, at the 1.9x dose level, maximum residues of thiabendazole and 5-hydroxy-thiabendazole were 0.017 and 0.42 ppm in kidney and 0.06 and 0.13 ppm in liver. Based on data from the metabolism study, maximum residues of benzimidazole are estimated to be 0.25 ppm in kidney and 0.09 ppm in liver at the 1.9x dose level. The maximum combined residues would be 0.687 ppm in kidney and 0.28 ppm in liver at the 1.9x dose level. These levels would be equivalent to combined residues of 0.36 and 0.15 ppm in kidney and liver at 1x the maximum dietary burden for beef cattle. Based on these data the tolerance for thiabendazole residues in meat-by-products (mbyp) of cattle, goats, horses, and sheep should be increased from 0.1 ppm to 0.4 ppm.

Table 4. Residue data for thiabendazole (TBZ) and 5-hydroxy-thiabendazole (5-OH-TBZ) from the ruminant feeding study.

Matrix	Dose Level (ppm) ^a	TBZ (ppm)		5-OH-TBZ (ppm)		Average Total Residues (ppm) ^b
		Range	Average	Range	Average	
Fat	0	0.017	NA	0.002	NA	0.019
	25	0.016-0.018	0.017	0.002-0.004	0.003	0.020
	75	0.013-0.017	0.015	0.009-0.012	0.010	0.025
	250	0.014-0.015	0.014	0.007-0.010	0.008	0.022
Kidney	0	0.018	NA	0.009	NA	0.027
	25	0.012	0.012	0.038-0.049	0.044	0.056
	75	0.016-0.017	0.016	0.079-0.421	0.25	0.266
	250	0.024-0.030	0.027	0.332-0.546	0.44	0.467
Liver	0	0.016	NA	0.012	NA	0.028
	25	0.022	0.022	0.026-0.028	0.027	0.049
	75	0.036-0.060	0.048	0.041-0.130	0.086	0.134
	250	0.056-0.080	0.068	0.121-0.156	0.138	0.206
Muscle	0	0.015	NA	0.003	NA	0.018
	25	0.012-0.014	0.015	0.002-0.003	0.002	0.017
	75	0.013-0.014	0.014	0.004-0.006	0.005	0.019
	250	0.015-0.017	0.016	0.004-0.005	0.004	0.020
Milk ^c	0	0.012-0.019	0.015	0.001-0.005	0.003	0.018
	25	0.013-0.015	0.014	0.009-0.013	0.012	0.026
	75	0.014-0.015	0.014	0.059-0.108	0.084	0.098
	250	0.014-0.017	0.016	0.072-0.134	0.111	0.127

^a The 25, 75, and 250 ppm dose levels are respectively equivalent to 0.7x, 1.9x, and 6.7x the maximum theoretical dietary burden of beef cattle and 1x, 2.9x, and 9.6x the maximum theoretical dietary burden of dairy cattle.

^b Sum of the average TBZ and 5-OH-TBZ residues; data from individual samples were not available.

^c Residue data are from milk samples collected after 1, 2, 4, 6, 7, 14, 21, and 28 days of dosing for treated animals, and on days 14, 21, and 28 for control animals.

The dose levels used in the ruminant feeding study are equivalent to 4.9x, 14.7x, and 49x the maximum dietary burden for swine (5.1 ppm). Based on the residue data for ruminants and the dietary burden for swine, HED concludes that there is no reasonable expectation of finding finite thiabendazole residues in meat and fat of hogs [40 CFR 180.6(a)(3)]; therefore, tolerances for thiabendazole residues in fat of hogs should be revoked. The tolerance for thiabendazole residues in meat of hogs will be retained at 0.1 ppm to harmonize with Codex. However, because the maximum combined residues would be 0.687 and 0.28 ppm in kidney and liver, respectively, at a 14.7x dose level, tolerances for thiabendazole residues in hog, mbyp should be set at the

combined LOQ (0.3 ppm) for the analytes in the proposed enforcement method. Therefore, the tolerance for thiabendazole residues in hog, mbyb should be increased from 0.1 ppm to 0.3 ppm.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

As the registrant is not supporting the use of thiabendazole on rice, data on thiabendazole residues in potable water, fish, and irrigated crops are no longer required.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-handling Establishments

Thiabendazole is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

Provided information on sample storage intervals is submitted along with adequate data supporting the stability of benzimidazole and 5-hydroxy-thiabendazole in frozen samples for those intervals, the available confined rotational crop study is adequate.

Radioactive residues in rotational crops grown in thiabendazole-treated (1.92 lb ai/A, 1x) soil were adequately identified/characterized. The metabolic profile in rotational crops is qualitatively similar to the profile in primary crops with the exception of 5-hydroxy-thiabendazole. At plant-back intervals of up to 320 days, the principle residues identified were thiabendazole, accounting for 10.5-74.1% of the TRR, and benzimidazole (free and conjugated) accounting for <1-63.2% of the TRR. The metabolite 5-hydroxy-thiabendazole, which is currently a regulated residue in animal commodities, was also identified as a minor component (<1.0-14.6% TRR) of the residue in each commodity. The HED Metabolism Assessment Review Committee concluded the metabolite 5-hydroxy-thiabendazole would not be included in tolerance definition for thiabendazole residues in rotational crops and 5-hydroxy-thiabendazole determination in limited field rotational crop studies would not be required (T. Morton, 12/2/99, D261103).

In the rotational crop commodities, the combined residues of thiabendazole and benzimidazole (free and conjugated) were 0.05-4.64 ppm at the 30-day PBI, 0.02-1.69 ppm from the 120-day PBI, and 0.11-5.04 ppm from the 320-day PBI.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops:

Limited field rotational crop studies at the maximum application rate are required as thiabendazole residues of concern were >0.01ppm in all RACs at each PBI in the confined rotational crop study. Samples must be analyzed for thiabendazole and benzimidazole (free and conjugated). For information on conducting limited field accumulation studies on rotational crops, the registrant should refer to OPPTS Guideline No. 860.1900.

There are presently no rotational crop restrictions on thiabendazole end-use products with uses on rotational crops. Based upon the results from the confined study, rotational crop restrictions, to be determined from the limited field rotational crop studies, are required on labels for products with field crop uses.

Table A. Food/Feed Use Patterns Subject To Reregistration for Thiabendazole (Case 2670).

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations ^a
Banana and plantain					
Post-harvest Spray until run-off	3.8 lb/gal FIC [100-889]	0.08 lb ai/26.4 gal (~400 ppm)	1	Not applicable (NA)	
Carrots					
Post-harvest dip	3.8 lb/gal FIC [100-889]	1.25 lb ai/100 gal (~1550 ppm)	1	NA	Maximum treatment time of 10 minutes.
Citrus					
Sequential post-harvest aqueous dip and wax	NA ^b	5000 ppm (1 gal wax/3500 lb of fruit)	2	NA	Thiabendazole is first applied as an aqueous dip at up to 1,000 ppm for up to 3 minutes prior to de-greening, followed by a second application (after de-greening and washing) of Thiabendazole at up to 3,500 ppm in wax (1 gal wax/3,500 lb of fruit). In AZ and CA, only a single post-harvest application is allowed as an application of thiabendazole in wax at up to 5,000 ppm (1 gal wax/3,500 lb of fruit).
Mushrooms					
Direct spray or in irrigation water at casing, fuzzing, pinning, and between breaks	3.8 lb/gal FIC [100-889]	0.24 lb ai/1000 ft ²	4	NS	A 12-hour PHI is specified. The label specifies that a maximum of 0.6 lb ai/1000 ft ² or 0.48 lb ai/1000 ft ² may be applied to each crop using irrigation water or direct spray (hand-sprayer) applications, respectively.
Pome fruits					
Post-harvest dip, flood, or spray	3.8 lb/gal FIC [100-889]	0.48 lb ai/100 gal (~600 ppm)	2	NS	Maximum treatment time of 3 minutes. Apples may be treated before and after storage; pears may only be treated once.

Table A (continued).

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations ^a
Potatoes					
Post-harvest mist application	3.8 lb/gal FIC [100-889]	0.0125 lb ai/2000 lb tubers	2	30	A second mist or 20-second dip application (0.0125 lb ai/gal water) may be applied after storage; do not treat seed potatoes after cutting.
Seed tubers prior to cutting			1	NA	
Soybeans					
Seed treatment Slurry or dispersion	NA ^b	0.003 lb ai/100 lb seed	1	NA	The label prohibits grazing or feeding treated soybean vines or hay to livestock.
Sweet Potatoes					
Pre-planting dip to seed roots	3.8 lb/gal FIC [100-889]	0.24 lb ai/7.5 gal	1	NA	Seed roots may be treated for a maximum of 10 minutes, and planted immediately. The labels prohibits the use of treated seed roots for food or feed.
Tobacco					
Broadcast foliar applications to seedlings in seed beds prior to transplant.	3.8 lb/gal FIC [100-889]	0.57 oz ai/1000 ft ²	3	NS	Initial foliar application to tobacco seed beds at 0.37 oz ai/1000 ft ² when seedlings are dime- sized, followed by two applications at 0.57 oz ai/1000 ft ² two weeks after the first, and near transplanting, for a total of 1.51 oz ai/1000 ft ² (4.11 lb ai/A). The proposed application volume is 1 gal/1000 ft ² .
Post-harvest application to reconstituted tobacco leaf	40% RTU [100-887]	1 oz ai/100 lb bone-dry tobacco	1		The label directions specify adding 1 oz ai of thiabendazole to the tobacco water stream for each 100 lb of bone-dry tobacco, prior to reconstitution of the tobacco.
Wheat					

Table A (continued).

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations ^a
Seed treatment Slurry or dispersion	2.7 lb/gal FIC [100-890]	3.6 oz ai/100 lb of seed	1	NA	The label prohibits grazing or feeding treated green forage to livestock.
The following uses are registered for non-US application.					
Avocado (import use)					
Post-harvest dip		3240 ppm	1	NA	Residue data support a maximum treatment time of 30 seconds and a maximum dip concentration of 3240 ppm.
Cantaloupe (import use)					
Direct foliar spray		0.27 lb ai/acre	3		Residue data support a maximum application rate of 0.27 lb ai/acre applied 3 times with a PHI of 4 days. Additional residue data for benzimidazole (free and conjugated) are required.
Mango (import use)					
Post-harvest dip		3240 ppm	1	NA	Residue data support a maximum treatment time of 30 seconds and a maximum dip concentration of 3240 ppm.
Papaya (import use)					
Post-harvest dip		2000 ppm	1	NA	Residue data support a maximum treatment time of 30 seconds and a maximum dip concentration of 2000 ppm.
Strawberry (import use)					

Table A (continued).

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations ^a
Direct foliar spray		0.53 lb ai/acre	1	NA	Residue data support a maximum application rate of 0.53 lb ai/acre applied once with a PHI of 14 days. Additional residue data for benzimidazole (free and conjugated) are required.

^a EP label EPA Reg No. 100-889 prohibits applications through any type of irrigation system.

^b A REFS search dated 10/7/98 listed no thiabendazole end-use products registered to Novartis for use on citrus. These use directions represent the use supported by Merck as indicated in a 6/26/94 meeting with the Agency, and a subsequent letter (D. Miller, 8/10/94). In addition, these directions for use reflect the use pattern depicted in the recently submitted citrus residue field trial data (DP Barcode D207850, 1/8/99, S. Mason).

Table B. Residue Chemistry Science Assessments for Reregistration of Thiabendazole.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A	Yes ²	See Table A.
860.1300: Plant Metabolism	N/A	No	41872901 ³ 41872902 ³ 41872903 ³
860.1300: Animal Metabolism	N/A	No	42011701 ⁴ 42057901 ⁴
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	Yes ⁵	42718401 ⁶ 43328301 ⁷ 43328302 ⁷ 43328303 ⁷ 43328307 ⁷ 43547601 ⁸ 43721902 ⁷ 43721903 ⁷ 43721904 ⁷
- Animal commodities	N/A	Yes ⁹	00123329 40271706 40271707 40789815 40789817 40789818 43251501 ¹⁰ 43251503 ¹⁰ 43251504 ¹⁰
860.1360: Multiresidue Methods	N/A	Yes ¹¹	
860.1380: Storage Stability Data	N/A	Yes ¹²	40271706 40271707 40789816 40789817 40789818 42515802 ¹³ 42568001 ¹⁴ 42718401 ⁶ 42868701 ¹⁵ 43251502 ¹⁰ 43251505 ¹⁰ 43531001 ⁸ 43547601 ⁸
860.1500: Crop Field Trials			
<u>Root and Tuber Vegetables Group</u>			
- Carrots	10.0 [§180.242(a)]	No	00123302 00123303
- Potato	10.0 [§180.242(a)]	No	42660302 ¹⁶ 43531002 ⁸ 43547601 ⁸
- Sweet potato	0.02 [§180.242(a)]	Yes ¹⁷	42660301 ¹⁶ 43531002 ⁸ 43547601 ⁸
- Sugar beets	0.25 [§180.242(a)]	No ¹⁸	
<u>Leaves of Root and Tuber Vegetables Group</u>			
- Sugar beet tops	10.0 [§180.242(a)]	No ¹⁸	
<u>Legume Vegetables Group</u>			

Table B. (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Beans, dry	0.1 [§180.242(a)]	Yes ²³	
- Lentils	0.1 [§180.242(a)]	Yes ¹⁹	
- Soybeans	0.1 [§180.242(a)]	Yes ²³	
<u>Foliage of Legume Vegetables Group</u>			
- Soybean, forage and hay	None	Yes ²³	
<u>Cucurbit Vegetables Group</u>			
- Cantaloupes	15.0 [§180.242(a)]	Yes ²⁰	
- Squash, Hubbard	1.0 [§180.242(a)]	No ²¹	
<u>Citrus Fruits Group</u>	10.0 [§180.242(a)]	No	42568001 ^{14,22} 43328306 ⁷ 43328307 ⁷ 43721904 ⁷
<u>Pome Fruits Group</u>			
- Apples	10.0 [§180.242(a)]	No	42515802 ¹³ 43721903 ⁷
- Pears	10.0 [§180.242(a)]	No	42515801 ¹³ 43721903 ⁷
<u>Cereal Grains Group</u>			
- Rice, rough	3.0 [§180.242(a)]	No ¹⁸	
- Wheat, grain	1.0 [§180.242(a)]	Yes ²³	42718401 ⁶ 43328301 ⁷ 43328302 ⁷
<u>Forage, Fodder, and Straw of Cereal Grains Group</u>			
- Rice, straw	10.0 [§180.242(a)]	No ¹⁸	
- Wheat, straw	1.0 [§180.242(a)]	Yes ²³	42718401 ⁶ 43328301 ⁷ 43328302 ⁷
<u>Miscellaneous Commodities</u>			
- Avocados	10.0 [§180.242(a)]	No ¹⁸	

Table B. (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Bananas	3.0 [§180.242(a)]	No	42868701 ¹⁵ 43721901 ⁷ 43721902 ⁷
- Grapes	10.0 [§180.242(a)]	No ¹⁸	
- Mangoes	10.0 [§180.242(a)]	No ¹⁸	
- Mushrooms	40.0 [§180.242(a)]	No	42598901 ²⁴ 43531001 ⁸
- Papayas	5.0 [§180.242(a)]	No ¹⁸	00071747 00071748 00071749 00071750 00123334 00123335
- Strawberries	5.0 [§180.242(a)]	Yes ²⁰	
- Tobacco	NA	Yes ²⁵	42905201 ²⁶
860.1520: Processed Food/Feed			
- Apple	None	No	42515802 ¹³ 43721903 ⁷
- Citrus, dried pulp	35.0 [§180.242(a)]	No	42568001 ¹⁴ 43328306 ⁷
- Potato, processing waste	30.0 [§180.242(a)]	No	42660302 ¹⁶ 43531002 ⁸
- Rice, hulls	8.0 [§180.242(a)]	No ¹⁸	
- Soybean	None	No ²³	
- Sugar beets, dried pulp	3.5 [§180.242(a)]	No ¹⁸	
- Wheat, milled fractions (exc. flour)	3.0 [§180.242(a)]	No	42718401 ⁶
860.1480: Meat, Milk, Poultry, and Eggs			
- Meat, Meat-by-products, and fat of cattle, goats, hogs, horses, and sheep	0.1 [§180.242(b)]	No	40789817
- Milk	0.4 [§180.242(b)]	No	40789817
- Meat and Meat-by-products of poultry	0.1 [§180.242(b)]	No	00123329
- Eggs	0.1 [§180.242(b)]	No	00123329

Table B. (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1400: Water, Fish, and Irrigated Crops	None	No ²⁷	
860.1460: Food Handling	None	NA	
860.1850: Confined Rotational Crops	N/A	Yes ²⁸	42367801 ²⁹
860.1900: Field Rotational Crops	None	Yes ³⁰	
<ol style="list-style-type: none"> References were reviewed in the Thiabendazole Phase 4 Review dated 2/20/91, unless otherwise noted. Based upon the available residue data and/or changes in data requirements, the Agency is recommending changes to use directions. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under <u>Directions for Use</u>. CB No. 8192, DP Barcode D165718, L. Cheng, 3/11/92. CBRS Nos. 8930 and 8719, DP Barcodes D170818 and D169697, L. Cheng, 3/2/92. The proposed HPLC/fluorescence enforcement method for determining residues of benzimidazole (free and conjugated) in plant commodities should be forwarded to the Analytical Chemistry Branch for Agency validation. CBRS No. 11792, DP Barcode D190451, L. Cheng, 7/28/93. CBRS Nos. 14477 and 14248, DP Barcodes D207850 and D218096, S. Mason, 1/8/99. CBRS No. 15434, DP Barcode D214188, S. Mason, 1/12/99. Additional data are required for Merck Method M-027. The method should be validated at levels of 0.05 ppm for each analyte. The HPLC/fluorescence detection methods for determining residues of thiabendazole and 5-hydroxy-thiabendazole (free and conjugated) in milk (Merck Method M-028.1) and thiabendazole, 5-hydroxy-thiabendazole (free and conjugated), and benzimidazole in animal tissues (Merck Method M-027) will be forwarded to the Analytical Chemistry Branch for validation by the Agency when additional data for M-027 is submitted. As tolerances for poultry commodities are no longer required, additional data and Agency validation are not required for Merck Method-025.1 for determining thiabendazole residues in eggs. CBRS No. 13991, DP Barcode D205191, S. Mason, 12/30/98. Data are required depicting recovery of the metabolites 5-hydroxy-thiabendazole and benzimidazole through FDA Multiresidue Protocols. Data are required depicting the storage stability of thiabendazole and benzimidazole in sweet potatoes stored frozen for up to 52 months. CBRS No. 10954, DP Barcode D185173, R. Perfetti, 4/15/93. 			

15. CBRS No. 12715, DP Barcode D196149, F. Suhre, 4/14/94.
Table B (continued).

16. CBRS No. 11601, DP Barcode D189323, J. Abbotts, 8/3/93.
14. CBRS No. 11216, DP Barcode D186592, J. Abbotts, 7/30/93.
17. To support the sweet potato field trials, data are required depicting the storage stability of thiabendazole and benzimidazole in sweet potatoes stored frozen for up to 52 months (DP Barcode D214188, S. Mason, 1/12/99).
18. The registrant is not supporting uses on dry beans, grapes, rice, hubbard squash, and sugar beets.
19. Data are required on thiabendazole residues in/on lentils grown from seed treated with thiabendazole (FIC) at 1.2 oz. ai/100 lb of seed if the registrant intends on supporting this use. A Section 18 Exemption was granted for this use in 1997 (DP Barcodes D234720 and D234721, M. Ottley/B. Tarplee/N. Dodd, 8/6/97) along with a temporary tolerance of 0.1 ppm for residues in/on lentils which expired 10/31/98.
20. The registrant is supporting a tolerance with no U.S. registration for cantaloupe and strawberry. Residue data is for parent only. Additional residue data are required for benzimidazole, free and conjugated.
21. There are currently no uses for thiabendazole on hubbard squash. The Phase 4 Review (2/20/91) indicated that IR-4 would like to support the established tolerance; however, a proposed use pattern and residue data have not been submitted.
22. CBRS No. 14013, DP Barcode D205192, D. Miller, 8/10/94.
23. Residue data are required on thiabendazole residues in/on wheat, dry beans (if registrant intends to support due to numerous SLNs), and soybeans grown from seed treated with thiabendazole. No residue data are available for this use pattern. A processing study is required for the processed fractions of soybeans.
24. CBRS No. 11161, DP Barcode D186572, D. Miller, 11/22/93.
25. Sufficient data are available to support the use of thiabendazole on tobacco seedlings prior to transplanting. However, data are required supporting the post-harvest use during reconstitution of dried tobacco. Residue data are required depicting thiabendazole residues of concern in/on reconstituted tobacco following treatment with thiabendazole at 1 oz ai/100 lb dried tobacco. Details of the reconstitution process and any subsequent processing of the tobacco prior to making cigarettes should be provided. If residues of concern exceed 0.1 ppm in/on reconstituted tobacco, then a radiolabelled pyrolysis study will be required to identify and quantify pyrolysis products.
26. DP Barcode D195001, G. Kramer, 2/28/94.
27. Residue data thiabendazole in water, fish, and irrigated crops will not be required provided all uses on rice are deleted from the registrant's labels.
28. Information is required on the sample storage intervals in the confined rotational crop study, along with data indicating the stability of benzimidazole and 5-hydroxy-thiabendazole in samples held in frozen storage for the intervals used in the study.
29. DP Barcode D180331, J. Punzi, 4/8/98.
30. Limited field rotational crop studies are required as thiabendazole residues of concern were >0.01ppm in all RACs at each PBI in the confined rotational crop study. For information on conducting limited field accumulation studies on rotational crops, the registrant should refer to OPPTS Guideline No. 860.1900.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for thiabendazole residues are currently expressed in terms of thiabendazole *per se* in or on plant commodities and mushrooms [40 CFR §180.242 (a)] and expressed as the combined residues of thiabendazole and 5-hydroxy-thiabendazole in animal commodities [40 CFR §180.242 (b)]. For purposes of tolerance enforcement, thiabendazole residues of concern have been determined to include thiabendazole and its metabolite benzimidazole (free and conjugated) in plant commodities. For animal commodities, thiabendazole, 5-hydroxy-thiabendazole (free and conjugated), and benzimidazole have been determined to be the residues of concern in animals. Accordingly, the tolerance definition for thiabendazole residues listed under 40 CFR 180.242 (a) should be amended to read as follows:

Tolerances are established for the combined residues of thiabendazole [2-(4-thiazolyl) benzimidazole] and its metabolite benzimidazole (free and conjugated) in or on the following raw agricultural commodities:

In addition, the tolerance definition for thiabendazole residues in animal commodities listed under 40 CFR 180.242 (b) should be amended to read as follows:

Tolerances are established for the combined residues of thiabendazole [2-(4-thiazolyl) benzimidazole] and its metabolites 5-hydroxy-thiabendazole (free and conjugated) and benzimidazole in or on the following raw agricultural commodities:

A summary of the thiabendazole tolerance reassessment for the above commodities and recommended modifications in commodity definitions are presented in Table C.

Tolerances Listed Under 40 CFR §180.242 (a):

Provided that the requested label amendments are made, sufficient data are available to reassess tolerances for thiabendazole residues in/on apples, bananas, carrots, citrus fruits, mushrooms, papayas, pears, and potatoes. Additional data are required for cantaloupe, sweet potatoes, wheat grain, wheat straw, soybean, and strawberry before the existing tolerance can be reassessed.

Based upon the current use patterns and the available residue data, the established tolerances are adequate for thiabendazole residues in/on bananas, carrots, citrus fruits, mushrooms and potatoes. Although additional storage stability data are required to support the sweet potato field trial data, the available data indicate the established tolerance should be increased to 0.05 ppm.

The tolerance for thiabendazole residues in banana pulp should be revoked as it is not a regulated commodity of banana. Tolerances should also be revoked for thiabendazole residues in/on sugar beet RACs and processed fractions, grapes, rice RACs and processed fractions, and hubbard squash as uses on these crops are not being supported by the registrant.

Based upon the available citrus, potato, and wheat processing studies, thiabendazole residues do not concentrate in potato and wheat processed fractions, and do not concentrate in dried citrus

pulp in excess of the tolerance on whole citrus fruits. Therefore, tolerances for residues in dried citrus pulp, potato processing waste, and wheat milled fractions should all be revoked.

There is a time-limited tolerance of 0.1 ppm for thiabendazole residues in/on lentils based upon a Section 18 Exemption which expired 10/31/98.

Tolerances Listed Under 40 CFR §180.242 (b):

Sufficient data are available to reassess tolerances for thiabendazole residues in animal commodities. Although benzimidazole, a residue of concern in animals, was not determined in the feeding studies, data from the animal metabolism studies will be used to calculate residue levels of benzimidazole in animal commodities for purposes of tolerance reassessment and risk assessment. In addition, data from the ruminant feeding study were used to reassess tolerances in hogs.

Based on the maximum dietary burden for poultry (0.16 ppm) and data from the poultry feeding study, a Category 3 [40 CFR §180.6(a)(3)] situation exists for thiabendazole residues in poultry commodities. Therefore, tolerances for residues in poultry meat, mbyp, and eggs should be revoked.

Based on the maximum dietary burden for beef cattle (37.6 ppm) and swine (5.1 ppm) and the data from the ruminant feeding study, a Category 3 [40 CFR §180.6(a)(3)] situation also exists for thiabendazole residues in meat and fat of cattle, hogs, horses, goats, and sheep. Therefore, tolerances for residues in fat of cattle, hogs, horses, goats, and sheep should be revoked. The tolerance for meat of cattle, hogs, horses, goats, and sheep will be retained at 0.1 ppm to harmonize with Codex. However, these data also indicate that tolerances for thiabendazole residues in mbyp of cattle, horses, goats, and sheep should be increased to 0.4 ppm and that the tolerance for residues in hog, mbyp should be increased to 0.3 ppm. In addition, the tolerance for thiabendazole residues in milk should be decreased to 0.1 ppm based on data from the ruminant feeding study and a maximum dietary burden of 26.1 ppm for dairy cattle.

Tolerances Needed Under 40 CFR §180.242 (a):

New tolerances are needed for thiabendazole residues in/on wet apple pomace, citrus oil, pome fruits, and wheat forage and hay. At the present time, sufficient data are only available to determine appropriate tolerances for residues in wet apple pomace and citrus oil. Residue data are required before an appropriate tolerance can be determined for residues in/on wheat forage and hay.

A tolerance of 12.0 ppm is required for thiabendazole residues in wet apple pomace based upon the 3.5x concentration factor and HAFT residues of 3.4 in/on apples. A tolerance of 15.0 ppm is required for thiabendazole residues in citrus oil based upon the average 2.4x concentration factor and HAFT residues of 5.2 in/on whole citrus fruits.

In addition, a crop group tolerance should be established for residues in/on pome fruits at 5.0 ppm based upon the available residue data on apples and pears. Once the tolerance is established on pome fruit, the separate tolerances on apples and pears should be revoked.

A temporary tolerance for thiabendazole residues in/on lentils at 0.1 ppm expired 10/31/98. If the registrant intends on supporting use of thiabendazole as a seed treatment on lentils, data are required on thiabendazole residues in/on lentils grown from seed treated with thiabendazole (FIC) at 1.2 oz. ai/100 lb of seed. Although IR-4 initiated residues studies on lentils in 1996, it is unclear if any registrant (Novartis or Gustafson) is continuing to support this use.

Table C. Tolerance Reassessment Summary for Thiabendazole.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR §180.242 (a):			
Apples (post-h)	10.0	Revoke	Concomitant with establishing a 5.0 ppm tolerance on Pome fruits, the tolerance on apples should be revoked.
Avocados	10.0	10	Registrant is supporting avocado for import only. <i>Avocado</i>
Bananas (pre & post-h)	3.0	3.0	<i>Banana</i>
Banana, pulp	0.4	Revoke	Banana pulp is not a regulated commodity of banana.
Banana, pulp (post-h)	0.4		
Beans, dry	0.1	0.1	Numerous SLNs registered. <i>Bean, dry</i>
Beets, sugar, pulp, dehydrated	3.5	Revoke	Registrant is not supporting this use.
Beets, sugar, pulp, dried	3.5	Revoke	
Beets, sugar, tops	10.0	Revoke	
Beet, sugar, without tops	0.25	Revoke	
Cantaloupes (post-h)	15.0	TBD	Registrant is supporting cantaloupe for import only. <i>Cantaloupe</i>
Carrots (post-h)	10.0	10.0	<i>Carrot</i>
Citrus fruits (post-h)	10.0	10.0	<i>Fruit, citrus, group</i>
Citrus, pulp, dried (post-h)	35.0	Revoke	Data indicate that thiabendazole residues do not concentrate in dried pulp in excess of the 10 ppm tolerance established in/on whole fruit.
Grapes	10.0	Revoke	No registered uses on grapes.
Lentils	0.1 ^a	Revoke	Temporary tolerance expired 10/31/98.
Mangoes	10.0	10.0	Registrant is supporting mango for import only. <i>Mango</i>
Mushrooms	40.0	40.0	<i>Mushroom</i>
Papayas (post-h)	5.0	5.0	Registrant is supporting papaya for import only. <i>Papaya</i>
Pears (post-h)	10.0	Revoke	Concomitant with establishing a 5.0 ppm tolerance on Pome fruits, the tolerance on pears should be revoked.
Potatoes (pre- & post-h)	10.0	10.0	<i>Potato</i>
Potatoes, processing waste (pre- & post-h)	30.0	Revoke	Data indicate that thiabendazole residues do not concentrate in potato processed commodities.

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Rice, rough	3.0	Revoke	Registrant is not supporting this use.
Rice, straw	10.0	Revoke	
Rice, hulls	8.0	Revoke	
Soybeans	0.1	TBD	Registrant is supporting seed treatment only. <i>Soybean, seed</i>
Squash, hubbard	1.0	Revoke	No registered uses on squash.
Strawberries	5.0	TBD	Registrant is supporting strawberry for import only. <i>Strawberry</i>
Sweet potatoes (post-h to SP intended only for use as seed)	0.02	0.05	Residue data support a higher tolerance. <i>Sweet potato, roots</i>
Wheat, grain	1.0	TBD	Residue data support a lower tolerance.
Wheat, straw	1.0	TBD	Residue data support a lower tolerance.
Wheat, milled fractions (excluding flour)	3.0	Revoke	Data indicate that thiabendazole residues do not concentrate in wheat processed commodities.
Tolerances listed under 40 CFR §180.242(b):			
Cattle, meat	0.1	0.1	A category 40CFR180.6(a)(3) situation exists for the potential of thiabendazole residues in meat and fat of livestock.*
Cattle, fat	0.1	Revoke	
Cattle, mbyp	0.1	0.4	Residue data indicate that the tolerance should be increased. <i>Cattle, meat byproducts</i>
Milk	0.4	0.1	Tolerance should be lowered based on data from ruminant feeding study
Hog, meat	0.1	0.1	A category 40CFR180.6(a)(3) situation exists for the potential of thiabendazole residues in meat and fat of livestock.*
Hog, fat	0.1	Revoke	
Hog, mbyp	0.1	0.3	Residue data indicate that the tolerance should be increased. <i>Hog, meat byproducts</i>
Horse, meat	0.1	0.1	A category 40CFR180.6(a)(3) situation exists for the potential of thiabendazole residues in meat and fat of livestock.*
Horse, fat	0.1	Revoke	
Horse, mbyp	0.1	0.4	Residue data indicate that the tolerance should be increased. <i>Horse, meat byproducts</i>
Goat, meat	0.1	0.1	A category 40CFR180.6(a)(3) situation exists for the potential of thiabendazole residues in meat and fat of livestock.*

Table C (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Goat, fat	0.1	Revoke	
Goat, mbyp	0.1	0.4	Residue data indicate that the tolerance should be increased. <i>Goat, meat byproducts</i>
Sheep, meat	0.1	0.1	A category 40CFR180.6(a)(3) situation exists for the potential of thiabendazole residues in meat and fat of livestock.*
Sheep, fat	0.1	Revoke	
Sheep, mbyp	0.1	0.4	Residue data indicate that the tolerance should be increased. <i>Sheep, meat byproducts</i>
Poultry, mbyp, and meat	0.1	Revoke	A category 40CFR180.6(a)(3) situation exists for the potential of thiabendazole residues in poultry commodities.
Eggs	0.1		
Tolerances needed under 40 CFR §180.242 (a)			
Apple, wet pomace	None	12.0	Based on a 3.5x concentration factor for wet apple pomace and HAFT residues of 3.4 ppm in/on apples
Citrus, oil	None	15.0	Based on an average 2.4x concentration factor for citrus oil and HAFT residues of 5.2 ppm in/on citrus fruits
Fruit, pome, group	None	5.0	Residue data support establishing a 5.0 ppm tolerance on pome fruits; the separate tolerances on apples and pears should be revoked.
Wheat, forage	None	TBD	Data are required on thiabendazole residues in/on wheat forage and hay.
Wheat, hay	None	TBD	

^a Time limited tolerance which expired on 10/31/98.

* Tolerances in meat of cattle, goats, hogs, horses, and sheep are being retained to harmonize with Codex.

TBD = To be determined